

Notice of Allowability

Application No.

09/598,443

Examiner

Fozia M. Hamud

Applicant(s)

SIMS, JOHN ERNEST

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 04/28/05.
2. ☒ The allowed claim(s) is/are 39, 40, 46, 47, 53-60, (now renumbered 1-12, respectively).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

Examiner's Amendment:

1. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Attorney William K. Merkel on 29 November 2005.

2. The application has been amended as follows:

IN THE CLAIMS:

2a. Please cancel claims 34, 35, 36, 37, 38, 41, 42, 43, 44, 45, 48, 49, 50, 51 and 52 without prejudice or disclaimer.

2b. Please rewrite claims 39 and 40 as follows:

39 (once Amended) An isolated nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO:1.

40 (once Amended) An isolated nucleic acid molecule encoding the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2.

2c. In claims 55-58, line 1, after "claim" delete "48, 49, 50, 51, 52".

2d. In claim 59, line 2, after "claim" delete "48, 49, 50, 51, 52".

REASONS FOR ALLOWANCE:

3a. The rejections of claims 39, 40, 46, 47, 53-60 made under 35 U.S.C. 101/112, first paragraph, for not being supported by either a specific and substantial asserted utility or a well established utility, are withdrawn. The instant specification discloses that

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the claimed nucleic acid of SEQ ID NO:1, encodes a polypeptide that is a member of the IL-1 receptor family (Single Ig Interleukin-1 Receptor-Related or SIGIRR). The specification also discloses that the polypeptide encoded by the claimed nucleic acid has only one Ig domain, rather than the typical three Ig domains, and that it is involved in modulating inflammatory responses.

Applicants' argument that post filing date references corroborated the above teachings, was found persuasive. For example, Wald et al. (Nature Immunology, Vol. 4:920-927 (2003) confirms that SIGIRR is an IL-1 receptor family member, that does not enhance IL-1 activities, but rather regulates IL-1 activities negatively and that it is the only IL-1 receptor family member so far that contains only one Ig domain. O'Neill, Nature Immunology, 4:823-824 (2003), Mantovani et al. J. Leukocyte Biol. 75:738 (2004) and Polentarmino et al. Eur. Cytokine New, vol 14:211 (2003) all confirm that SIGIRR is a decoy receptor that negatively regulates IL-1 activity. Thus, each of these post-filed publications confirms Applicants' assertion in the application as filed that SIGIRR is a member of the IL-1 Receptor family and that it modulates inflammatory responses.

3b. The rejection of claims 59-60 made under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn, because claim 59 now recites "SIGIRR", which is an art recognized acronym.

Conclusion :

4. Claims 1-38, 41-45 and 48-52 are cancelled. Claims 39-40, 46-47 and 53-60 are allowed.

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Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
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01 December 2005